

Satish R. Shah
66 Lockwood Place
Clifton, NJ 07012

April 61, 71, 99, 99 MAY 25 A9:38

Mr. Gary J. Dykstra
Acting Associate Commissioner
for Regulatory Affairs (FDA)
Dept. of Health and Human Services
Food and Drug Administration
HFD-7
WOC 2, Room: 3037
Rockville, MD 20857

RE: Docket No. 93N-0340

Re: "Response to FDA's Letter dated 3/17/99"
(Received by Mr. Shah on 3/26/99)

Dear Mr. Dykstra:

In response to your letter dated March 17, 1999, I would like to add more information in regard to termination of debarment.

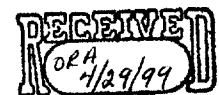
As you have indicated in your letter that "unless an applicant first clearly establishes that he or she provided substantial assistance" in the investigations or prosecutions of certain offenses, from all the documents previously submitted to the FDA, it is very clear that I was the first employee from Par Pharmaceutical and from the entire generic industry to come forward and wrote to Dr. Marvin Siefe, Director of Generic Drugs at that time about criminal activity occurring at Par Pharmaceutical during my employment.

I started helping the FDA and federal authorities from the first meeting with Mr. Holland, which took place in early 1989. After that, I gave several interviews to Mr. Gary Tunkavige and other federal authorities until my indictment in June 1992. During those four years, I was very helpful to the FDA and federal authorities. Indication of this can be found in Mr. Gary Tunkavige's letter and Mr. Thomas Holland's letter (previously submitted to FDA).

Also, attached herewith, please find a copy of my 28 U.S.C. 2255 Petition to Vacate the Judgment to District of Maryland, which allows Petitioner to rectify any error that occurred during trial and also indicates ineffective assistance of counsel.

My 2255 Petition clearly indicates that the government is at fault to indict me and to prosecute me.

93N-0349



Letter to Mr. Gary G. Dykstra
RE: Docket No. 93N-0340
April 21, 1999
Page 2

Regardless, in reference to your Exhibit 5, in your letter you indicated that I provided false information to the DOJ and I was involved in a scheme to extort funds from Par in return for not providing certain information to the DOJ.

These allegations are not true because I was set up by Mr. Christopher Mead when I wrote a letter to Mr. Sawyer (President of PAR) in order to negotiate compensation for my wrongful discharge from the job. Neither in that letter nor in my conversation with Mr. Sawyer did I mention anything about withholding any information for money. In fact, I was truthful during the entire interview with Mr. Sawyer.

In reference to your statement about a government coverup with the FDA, please see my copy of 28 U.S.C. §2255 Petition.

In reference to your statement on page no. 2, _____ - need to be truthful (5), please see my proffer letter, dated October 16, 1989, which was given to me after several meetings with FDA inspectors and federal authorities. In fact, the government broke the promise of that agreement (please see my 28 U.S.C. §2255 Petition).

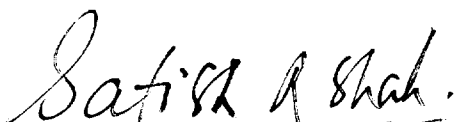
Repeatedly, you have mentioned about "untruthfulness" in your letter. The government has never indicated to me that I was "untruthful."

Finally, you have indicated on page 3 that I did not take responsibility for my own crimes, which meant the government had to expend significant resources to prosecute me, which is not true.

During my first interview with Mr. Holland in 1989, and in all other interviews with Mr. Gary Tunakavige and other federal authorities, in the presence of my attorney I described all the criminal activity that occurred at Par during my employment, for which I was given immunity from prosecution. In fact, the government was not truthful in labeling me as an honest person who came forward and helped the FDA and other federal authorities.

Finally, I respectfully submit this second request for termination of debarment.

Sincerely,


Satish R. Shah

Enc: Exhibits:

1. 28 USC 2255
2. proffer Letter

ROBERT H. CHESTER, ESQ.
377 Route 17 South, Suite 104
Hasbrouck Heights, New Jersey 07604
(201) 727-1803
Attorney for Petitioner, Satish R. Shah

UNITED STATES OF AMERICA

Plaintiff

v.

RATILAL K. ("R.K.") PATEL
ASHOK H. PATEL
SATISH R. SHAH
BARRY S. GELLER
NANDLAL G. RANA,

Defendants

FILED : ~~FILED~~ THE UNITED STATES DISTRICT COURT
LOADED : RECE

AUG 21 1997

CLERK U.S. DISTRICT COURT
DISTRICT OF MARYLAND
ORIGINAL

FOR THE
DISTRICT OF MARYLAND

CRIMINAL NO: 92-0255


CCB 97-2887

MOTION TO VACATE JUDGMENT UNDER 29 USC s 2255

To: Lynne Battaglia, Esq.
United States Attorney, District of Maryland
101 West Lombard Street, Room 6625
Baltimore, Maryland 21201

TAKE NOTICE that on the annexed petition of Satish R. Shah the indictment of the petitioner #92-0255 and on all the other papers and proceedings had herein, the undersigned will make application to the United States District Court, District of Maryland, 820 United States Courthouse, 101 West Lombard Street, Baltimore, Maryland, on September 27, 1997 at 9:00 A.M. or as soon thereafter as counsel may be heard, for an Order vacating and setting aside the sentence heretofore imposed upon the petitioner and discharging him from any and all probationary conditions and for such other, further or different relief as to this Court may seem just and proper.

Dated: August 13, 1997


ROBERT H. CHESTER, ESQ.
Attorney for Petitioner, Satish R. Shah

ROBERT H. CHESTER, ESQ.
377 Route 17 South, Suite 104
Hasbrouck Heights, New Jersey 07604
(201) 727-1803
Attorney for Petitioner, Satish R. Shah

UNITED STATES OF AMERICA
Plaintiff

: IN THE UNITED STATES DISTRICT
: COURT

v. FILED ENTERED
LOGGED RECEIVED

FOR THE
DISTRICT OF MARYLAND

RATILAL K. ("R.K.") PATEL
ASHOK H. PATEL
SATISH R. SHAH
BARRY S. GELLER
NANDLAL G. RANA,

AUG 21 1997
AT BALTIMORE
CLERK U.S. DISTRICT COURT
DISTRICT OF MARYLAND
CRIMINAL

CRIMINAL NO: 92-0255

Defendants

CCB-97-2887

PETITION OF SATISH R. SHAH

To: Honorable Judges of the United States District Court, District of Maryland

Petitioner, Satish R. Shah, respectfully represents:

1. That he was unjustly, unlawfully and illegally detained and imprisoned at the Federal Correctional Institution at Allenwood, Pennsylvania by color of the authority of the United States and is presently release on probation.
2. That he was sentenced on April 30, 1993 by this Court pursuant to a judgment of conviction of a violation of 18 U.S.C 1001 (false statements to the Food and Drug Administration).
3. That prior to his indictment he, together with counsel, met and conferred with agents of the United States Government at White Plains, New York. At such meeting a "proffer letter" pursuant to United States v. Kastigar was signed by the agents of the United States Government and him. At that time he disclosed his involvement in the falsification of testing data submitted by his employer Par Pharmaceutical, Inc. ("Par") to the governmental agents. His disclosure consisted of enumerated activities in which he and other employees of Par participated and which were the subject matter of the then pending investigation of both the United States Attorney's Office and the Food and Drug Administration.

Exhibit : 1

4. Shortly after the aforesaid conference at White Plains, New York he again was interviewed by investigators of the House Energy and Commerce Committees, Sub Committee on Oversight and Investigations. Again a proffer letter was signed and once more he disclosed to the Congressional Investigators his participation in the activities of Par in the falsification of scientific and testing data submitted to the Federal Drug Administration.
5. He made such disclosures in reliance upon the fact and the representation of the governmental officials that such disclosures would not be the basis of any subsequent prosecution against him and that the government were to choose to institute criminal proceedings against him would be constrained to prove his guilt by evidence independent from that disclosed by him.
6. Prior to trial, he consulted with his trial counsel and informed trial counsel that he had on at least two occasions voluntarily disclosed his participation in the falsification of scientific data.
7. He urged his trial counsel to make known to the Court of his disclosures to the government and to protect his rights not to have evidence of his involvement emanate from such disclosures as part of the evidence adduced at trial.
8. His trial counsel sought no protective relief from the Court. Accordingly, no hearing was held prior to trial to ensure that his statements given to the government officials were not the basis of the government's case and that the government's case would have to have an independent source prior to its admissibility into evidence.
9. During the trial, evidence was admitted bearing upon his guilt which resulted from his prior disclosures to government officials.
10. At no time did trial counsel, United States Attorney's Office or the Court attempt to analyze and exclude evidence which was solely based upon his factual disclosure.
11. Petitioner did not knowingly waive his constitutional rights under the Fifth and Sixth Amendment of the United States Constitution. The judgment of conviction was unlawful and unconstitutional as it was in violation of his rights.

Dated: August 13, 1997


SATISH R. SHAH



U.S. Department of Justice

GPJ:cwg
LTR10-16A

United States Attorney
District of Maryland

United States Courthouse, Eighth Floor
101 West Lombard Street
Baltimore, Maryland 21201-2692

301/539-2940
FTS/922-4822

October 16, 1989

David A. Biederman, Esquire
Chester & Biederman
One Parker Plaza
Fort Lee, New Jersey 07024

Re: Par Pharmaceutical, Inc.

Dear Mr. Biederman:

You have advised me that your client, Satish R. Shah, wishes to meet with the investigating agents and me for the purpose of making an "off-the-record" proffer in connection with the above matter. We are willing to meet with you and your client upon the following terms and conditions.

1. Except as otherwise provided in paragraphs two and three, no statements made or other information provided by you or your client during the proffer will be used against your client in any criminal case.

2. In order to avoid potential "taint" issues and obviate a Kastigar-type hearing, your client agrees that the Government may make derivative use of, and may pursue, any investigative leads suggested by any statements made or other information provided by you or your client during the proffer.

3. Your client's complete truthfulness and candor are express material conditions to the undertakings of the Government set forth in this letter. Therefore, the Government may use statements made or other information provided by you or your client during the proffer under the following circumstances:

a. In the event that your client is a witness in any proceeding related to this matter and offers testimony materially different from any statements made or other information provided by you or your client during the proffer, the attorney for the Government or other opposing party may cross-examine him concerning any statements made or other information provided by you or your client during the proffer.

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Exhibit "A" (E)

October 16, 1989

To: David A. Biederman, Esquire

Re: Par Pharmaceutical, Inc.

b. If your client knowingly withholds material information from the Government or otherwise is not being completely truthful and candid with the Government, the Government may use against him for any purpose (including sentencing), any statements made or other information provided by you or your client during the proffer. If the Government ever does so conclude, it will notify your client of our intent to make use of any such statements or other information. Whether or not your client has been untruthful or has knowingly withheld material information during the proffer shall be determined by the Court in an appropriate proceeding at which his disclosures shall be admissible and at which this office shall be required to establish his untruthfulness or withholding of material information by a preponderance of the evidence.

I trust that you will find these terms and conditions to be fair and reasonable. If your client wishes to make an "off-the-record" proffer to us in accordance with them, please sign and have your client sign this letter on the lines indicated below. Once signed, please return the original of the letter to me and retain the enclosed copy for your file.

Very truly yours,


Breckinridge L. Willcox
United States Attorney

By


Gary P. Jordan

First Assistant U.S. Attorney

Accepted:



Satish R. Shah


David A. Biederman, Esquire

Date

10/16/89



Satish R. Shah
66 Lockwood Pl
Clifton, NJ 07012-1932

Fold at line over top of envelope to
the right of the return address

CERTIFIED

Z 530 829 148

MAIL



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Mr. GARY J. DYKSTRA
Acting Associate Commissioner
for Regulatory Affairs (FDA)
Dept. of Health & Human Services
Food and Drug Administration (FDA)
~~HFD-7~~ (HFC-1; Rm. 14-90;
~~Woe 2, Room: 3037~~ PKW)
Rockville, MD. 20857

to HFD-7